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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/509,552	DJUPESLAND, PER GISLE	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16,18-28,30,31,35,36,38-41 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16,18-28,30,31,35,36,38-41 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendments filed January 21, 2010 and April 29, 2010. As directed by the amendment filed April 29, 2010, claims 28, 30, 31, 25--36, 38, and 40 have been amended; claims 2, 17, 29, 32-34, 37, and 42 are cancelled and claims 44-46 have been added. Thus, claims 1, 3-16, 18-28, 30-31, 35-36, 38-41 and 43-46 are pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-16, 18-28, 30-31, 35-36, 38-41 & 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland et al. (WO 00/51672), herein referred to as Djupesland '672, in view of Djupesland et al., (WO 01/97689 A1), herein referred to as Djupesland '689, and further in view of Alving et al (6,019,100).

Djupesland '672 discloses a nasal delivery device (figures 3 & 4) for delivering substance (via 32) to a nasal airway of a subject, comprising: first (34) and second (36) nosepiece units, each including a nosepiece (30 & 40) for fitting to respective nostrils of a subject; at least one substance supply unit (32) for supplying a metered dose of substance (page 18, lines 4-24) for delivery to the nasal airway of the subject; a valve (alternative embodiment of 28 as a biased flap as disclosed on page 17, line 21 - page 18, line 2); and a mouthpiece (26) through which the subject in use exhales to cause

closure of the oropharyngeal velum of the subject during delivery of substance (abstract). However, Djupesland '672 lacks the mouthpiece and two nosepiece units being fluidly connected together and a valve unit for selectively fluidly connecting the at least one supply unit alternatively to respective ones of the nosepiece units.

Djupesland '689 discloses a nasal delivery device (figures 5A-5D) that can be used for delivering a substance (via exhaled air) to a nasal airway of a subject, comprising: first (tube with 311 attached) and second (tube with 312 attached) nosepiece units, each including a nosepiece (311, 312) for fitting to respective nostrils of a subject; at least one substance supply unit (330) for supplying substance for delivery to the nasal airway of the subject; a valve unit (335 in figure 5B) for fluidly connecting the at least one substance supply unit to one of the nosepiece units; and a mouthpiece (310) through which the subject in use exhales to cause closure of the oropharyngeal velum of the subject during delivery of substance. See: page 17, line 15 - page 18, line 7. Djupesland '689 also discloses a three way valve that can be connected to the substance supply unit, but lacks the detailed description of the valve being used for selectively fluidly connecting a supply unit to respective nose piece units.

Alving teaches using a three way valve to alternatively connect tubes to the nostrils of a user. See: col. 6, lines 1-4 and figure 2.

It would have been obvious to one having ordinary skill in the art to have modified the metered dose nasal delivery device disclosed by Djupesland '672 by fluidly connecting the mouthpiece and nose piece units together and connecting them with a three way valve as taught by Djupesland '689 to selectively deliver medicament to either

nosepiece, as taught by Alving. This modification would be desirable in order to give patients the ability to selectively deliver the medicament to the nasal passage that is most comfortable and give them the ability to alternate between nasal passages in the event that one, or both, nasal passages becomes irritated or develops discomfort.

Regarding claim 3, Djupesland '672 discloses a gas supply channel (inside 34) for supplying a gas flow for entraining substance supplied by the at least one substance supply unit (32).

Regarding claim 4, Djupesland '672 discloses a mouthpiece (26) and Djupesland '689 teaches fluidly connecting the nosepiece (gas supply channel), whereby the gas flow is an air flow developed by an exhalation breath of the subject (via the mouthpiece). See: Djupesland '672, figures 5A-5D.

Regarding claim 5, Djupesland '672 teaches a gas supply unit (32) which is fluidly connected to the gas supply channel (inside 34) for delivering a gas flow through the gas supply channel. See: Djupesland '672, page 18, lines 18-23.

Regarding claim 6, Djupesland '672 discloses a gas supply unit (32) and an exhalation breath actuatable unit (via sensor 43, control unit 44 and medicament supply unit 32) which is fluidly connected to the mouthpiece, as taught by Djupesland '689, such as to be actuated on exhalation by the subject.

Regarding claim 7, Alving discloses a valve unit (See: col. 6, lines 1-4) that is configured alternately fluidly to connect one of the nosepiece units (tube with 311 attached) to the at least one substance supply unit (330) and vent the other of the nosepiece units (tube connected to 312), such that, where the gas flow is at a driving

pressure which is such as to cause the gas flow to flow around the posterior margin of the nasal septum and through the nasal airway, the gas flow delivered through the one nosepiece unit is vented through the other nosepiece unit. See: figures 5A-5D.

Regarding claim 8, Djupesland '672 discloses at least one flow resistor (41) to which the other nosepiece unit (36) is vented.

Regarding claim 9, Djupesland '689 discloses a flow resistor has a fixed flow resistance (page 7, lines 9-11) for providing a fixed flow resistance to the gas flow.

Regarding claims 10-11 Djupesland '672 discloses resistors that are adjustable to allow adjustment to the level of resistance and hence provide control of the dynamic pressure in the nasal airway and that the flow resistor can be a movable member such as a biased flap, a resilient member, or a damped wheel. See: page 20, lines 4-11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted one known resistor for another to produce the desired flow at the same pressure gradient as taught and suggested by Djupesland '689. See: page 5, lines 4-8.

Regarding claim 12, Djupesland '672 discloses a control unit (44) and Alving teaches the control unit (7) can be used for controlling the valve unit to alternate delivery of a substance through the nosepiece units.

Regarding claim 13, Djupesland '672 discloses a single substance supply unit (32) that can be used to supply a substance alternately to respective ones of the first and second nosepiece units via the valve taught by Djupesland '689 and the mechanism taught by Alving.

Regarding claim 14, Alving discloses a first (3A) and second (3B) substance supply units for supplying substance for delivery to respective ones of the first (tube with 311 attached) and second (tube with 312 attached) nosepiece units and it would be obvious to have utilized a separate substance supply unit for each nosepiece in order to ensure delivery of medicament in the event of failure of one substance supply unit.

Regarding claim 15, Djupesland '689 discloses a three-way valve which Alving teaches can function in the same manner as two one way valves to selectively connect a first and second nosepiece unit and it would have been obvious to a skilled artisan to chose a three way valve over two one way valves in order to for a more compact valve system that is easier to manipulate.

Regarding claim 16, Djupesland '672 discloses a method of delivering a metered dose substance (via 32) to a nasal airway of a subject by fitting first (30) and second (40) nosepiece units to respective nostrils of a subject; and exhaling through a mouthpiece (26) during delivery of substance to cause closure of the oropharyngeal velum of the subject and Alving teaches delivering substance alternately through respective ones of the nosepiece units.

Regarding claim 18, Djupesland '672 discloses a substance (via 32) that is delivered in a gas flow (via 34).

Regarding claim 19, Djupesland '689 discloses a gas flow as air flow developed by an exhalation breath of the subject. See: figures 5A-5D.

Regarding claim 20, Djupesland '672 discloses providing a gas flow (via 32) that is separate to an exhalation breath of the subject. See: page 18, lines 4-23.

Regarding claim 21, Alving teaches a substance that is delivered alternately to the nosepiece units and Djupesland '672 discloses that when the gas flow is at a driving pressure which is such as to cause the gas flow to flow around the posterior margin of the nasal septum and through the nasal airway, the gas flow delivered through the one nosepiece unit (30) is vented through the other nosepiece unit (40). See: page 18, line 25 - page 19, line 13.

Regarding claim 22, Djupesland '672 discloses the gas flow is vented through a flow resistor (41).

Regarding claim 23, Djupesland '689 discloses a flow resistor that has a fixed flow resistance (page 7, lines 9-11) and provides a fixed flow resistance to the gas flow.

Regarding claims 24-25 Djupesland '672 discloses resistors that are adjustable to allow adjustment to the level of resistance and hence provide control of the dynamic pressure in the nasal airway and that the flow resistor can be a movable member such as a biased flap, a resilient member, or a damped wheel. See: page 20, lines 4-11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted one known resistor for another to produce the desired flow at the same pressure gradient as taught and suggested by Djupesland '689. See: page 5, lines 4-8.

Regarding claim 26, Djupesland '672 discloses a substance (via 32) that is supplied from a single substance supply unit (32).

Regarding claim 27, Alving teaches a substance that is supplied to the first and second nosepiece units (figure 2) from respective ones of first (3A) and

second (3B) substance supply units and it would be obvious to have utilized a separate substance supply unit for each nosepiece in order to ensure delivery of medicament in the event of failure of one substance supply unit.

Regarding claim 28, Djupesland '672 discloses a nasal delivery device (Figures 7 & 9) for delivering substance to a nasal airway of a subject, with a mouthpiece (76 & 114) configured to receive an exhalation breath from the subject to cause closure of the oropharyngeal velum of the subject; at least on delivery unit (86 & 120) for delivering a metered dose substance (86 delivers a dry powder containing medicament and 120 delivers a metered volume of propellant containing medicament) to a nasal airway of the subject on exhalation by the subject; and an exogenous gas supply unit (via 72 of figure 7 and an aerosol propellant canister 120 of figure 9) is an exogenous gas supply unit) for supplying a gas flow into the nasal airway of the subject and Alving teaches alternating pressure via gas supply units (3A & 3B) for alternating pressure in the nasal airway of the subject during the exhalation breath. See: page 29, line 22 - page 31, line 7.

Regarding claim 30, Djupesland '672 discloses a gas supply unit (via 72 of figure 7 and an aerosol propellant canister 120 of figure 9) that is an exhalation breath actuatable unit (figures 7 & 8) which is fluidly connected to the mouthpiece as taught by Djupesland '689 such as to be actuated on exhalation by the subject. See: page 29, line 22 - page 31, line 7.

Regarding claim 31, Djupesland '672 discloses a method of delivering substance (via 86 in figure 7 & 120 of figure 9) to a nasal airway of a subject, comprising the steps

of delivering substance to a nasal airway of a subject; exhaling through a mouthpiece (76 of figure 7 & 114 of figure 9) during delivery of substance to cause closure of the oropharyngeal velum of the subject (See: page 29, line 22 - page 31, line 7); and applying a varying pressure in the nasal airway of the subject (based on the exhalation of the subject which will inherently vary during the breathing cycle) as taught by Djupesland '689 and supplying an exogenous gas flow having an alternating pressure into the nasal airway of the subject during the exhalation of breath (i.e. the pressure would alternate via the speed of the impeller (84 of figure 7 and the actuation of the aerosol container via the trigger mechanism of figure 9).

Regarding claim 35, Djupesland '672 discloses a nasal delivery device for delivering substance to a nasal airway of a subject, with a mouthpiece (76 of figure 7 & 114 of figure 9) configured to receive an exhalation breath from the subject to cause closure of the oropharyngeal velum of the subject (See: page 29, line 22 - page 31, line 7); at least one delivery unit (86 of figure 7 & 120 of figure 9) for delivering a metered dose of substance to a nasal airway of the subject during the exhalation breath; and Alving teaches a gas supply unit (4) that can be connected to pumps 3A and 3B to alternately delivering and withdrawing a volume of gas through the nasal airway of the subject on exhalation by the subject, such as to cause entrained substance to be flushed in alternate directions there through.

Regarding claim 36, Djupesland '672 discloses a method of delivering substance to a nasal airway of a subject (figures 7 & 9 of Djupesland '672), delivering substance to a nasal airway of a subject (See: page 29, line 22 - page 31, line 7); and the subject

delivering an exhalation breath through a mouthpiece (76 of figure 7 & 114 of figure 9) during delivery of the substance to cause closure of the oropharyngeal velum of the subject (See: page 29, line 22 - page 31, line 7); and Alving teaches a method of delivering a substance using a ventilator that is connected to pumps 3A & 3B that can be used to alternately deliver and withdraw gas through the nasal airway of the subject to cause entrained substance to be flushed in alternate directions there through.

Regarding claims 38, 45 & 46, the combined references disclose an interface member for attachment to a nasal delivery device, said interface member comprising, at least one nosepiece (82 & 132 of Djupesland '672) for fitting to a nostril of a subject and a mouthpiece (76 & 114 of Djupesland '672) comprising a cavity (inside 74 & 114 of Djupesland '672) into which the subject in use exhales, said cavity being closed off by a member (78 of figure 7 & 116 of figure 9) and figure 3 of (Djupesland '672) uses a closed flexible member (Djupesland discloses alternative embodiments of resistors as a biased flap as disclosed on page 29, line 22 - page 31, line 7) which is deflectable on exhalation into the mouthpiece so as to trigger a substance supply unit (32) in the nasal delivery device (82 & 132), and wherein the integral element (figure 7 of Djupesland '672) is configured such that no part of the delivery device (72) to which it is attached is exposed to the exhalation breath of the subject. Moreover, unifying the separate elements of figures 3 & 4 of Djupesland into a single one-piece configuration and using a flexible member would have been an obvious modification to a skilled artisan in order to form an easy to use, hand held, one-piece device that would function in the same way as the multi-piece device shown in figures 3-4. Moreover, Djupesland '672

discloses as an alternative the flow restrictor (28) can be a biased flap, a resilient membrane or a damped wheel, thus teaching a flexible member that comprises a resilient member. See: page 17, line 22 - page 18, line 2.

Regarding claim 39, Djupesland '672 discloses first (30) and second (40) nosepieces for fitting to respective nostrils of a subject.

Regarding claim 40, Djupesland '672 discloses an interface member (figures 7 & 9) that is a disposable element (any mechanical device has a finite useful life and is then disposable).

Regarding claim 41, Djupesland '672 discloses a mouthpiece comprises a tubular section (24) through which the subject in use exhales.

Regarding claim 43, Djupesland '672 discloses as an alternative the flow restrictor (28) can be a biased flap, a resilient membrane or a damped wheel, thus teaching a flexible member that comprises a resilient member. See: page 17, line 22 - page 18, line 2.

Regarding claim 44, it is the examiners position that one having ordinary skill in the art at the time the invention was made would have recognized that a diaphragm is encompassed by a resilient membrane, as disclosed by Djupesland '672. See: page 17, line 22 -page 18, line 2.

Response to Arguments

4. Applicant's arguments filed April 29, 2010 and January 21, 2010 have been fully considered but they are not persuasive.

Applicants argument that the collection reservoir (330 of Djupesland '689) is merely a conduit through which the exhaled air flow is directed to the nasal airway and is not configured to supply a metered dose of substance in the manner claimed by Applicant has not been found convincing, as a metered supply of medicament could be placed in the conduit and delivered to the patient, thus meeting the claimed limitation of "at least one substance supply unit for supplying a metered dose of substance for delivery to the nasal airway of the subject."

Regarding applicant's argument that the three-way valve (335) of Djupesland '689 does not fluidly connect the collection reservoir (330) to one of the nasal olives (311, 312), in the manner claimed by Applicant; applicant is reminded that Alving teaches using a three way valve to alternatively connect tubes to the nostrils of a user. See: col. 6, lines 1-4 and figure 2 and that it would have been obvious to one having ordinary skill in the art to have modified the metered dose nasal delivery device disclosed by Djupesland '672 by fluidly connecting the mouthpiece and nose piece units together and connecting them with a three way valve as taught by Djupesland '689 to selectively deliver medicament to either nosepiece, as taught by Alving. This modification would be desirable in order to give patients the ability to selectively deliver the medicament to the nasal passage that is most comfortable and give them the ability to alternate between nasal passages in the event that one, or both, nasal passages becomes irritated or develops discomfort.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. In the instant case, the

examiner has merely suggested that it would be desirable to alternate between nasal passages in the event that one, or both, nasal passages becomes irritated or develops discomfort.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding applicant's argument that the combined references lacks altogether a valve unit, as described in Applicant's independent claim 1, and the step of delivering a metered dose of substance alternately through respective nosepiece units, as described in Applicant's independent claim 16, the examiner respectfully reminds applicant that the valve unit was disclosed by Djupesland '689 as 335 in figures 5A-5D and Alving teaches using a three way valve to alternatively connect tubes to the nostrils of a user. See: col. 6, lines 1-4 and figure 2. The obvious reason for combining the references together is to give patients the ability to selectively deliver the medicament to the nasal passage that is most comfortable and give them the ability to alternate between nasal passages in the event that one, or both, nasal passages becomes irritated or develops discomfort.

Therefore, applicant's arguments have not been found convincing and the rejection has been MAINTAINED.

5. Regarding applicant's arguments that Alving does not disclose supplying a gas flow into the nasal airway of the subject and configured to provide an alternating pressure in the nasal airway of the subject during the exhalation breath and supplying an exogenous gas flow having an alternating pressure into the nasal airway of the subject during the exhalation breath, applicant's attention is drawn to the rejection of amended claims 28, 30-31, 35-36, 38-41 and 43-46 above, as Djupesland '672 teaches the newly claimed elements.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771